REMARKS

Applicant hereby requests further consideration of the present application in view of the amendments above and the comments that follow. Claims 1-29 and 34-73 are pending in the application.

I. The Section 112, Second Paragraph Rejection

The Action rejects Claim 23 as being indefinite as it is unclear as to whether the phrase "single solid elastomer" is intended to modify "endplates" or "body". Applicant has amended Claim 23 above to clarify the feature.

II. The Section 103 Rejections over U.S. 7,066,960 to Dickman ("Dickman")

The Action rejects Claims 1-3, 7, 9, 13-25 and 28 as being obvious over Dickman. The Action alleges that the claimed tensile strength of 100 KPa "would have been immediately obvious, if not inherent" from the reinforcing nature of the fabric (col. 7, lines 49-55). In addition, the Action contends that the claimed value of 0.01 N-m is a *minimal* torsion value and the Dickman device is capable of at least two degrees of rotation, so likewise such a rotation "would have been immediately obvious, if not inherent" from Dickman due to the fact that the implant can "resiliently absorb stresses associated with spinal rotation" Action, p. 3, citing col. 1, lines 25-30, col. 5, lines 33-64 and col. 8, lines 49-54 of Dickman.

Dickman describes a <u>reinforced</u> disk, *e.g.*, a unified <u>composite</u> disk prosthesis 40 <u>with a matrix 41 with a substrate of bioincorporable continuous fabric</u>. The central region intermixes a polymer such as a hydrogel polymer <u>with a substrate fabric</u> to form a nucleus (core) 42. Dickman states that a woven collagen fabric is preferred for its tensile strength (col. 8, lines 1-5). The substrate fabric within and outside the core can be separate (col. 7, lines 45-48). Outside the core, the substrate fabric is relatively devoid of the polymer with a fabric margin that runs to the edge of the disk and surrounds the core 42 (col. 7, lines 56-68). The disk 40 can be relatively solid but the structure of its matrix and core adapts it to undergo elastic deformation (col. 7, lines 60-65).

Applicant has amended Claim 1 as restated below for ease of discussion.

> 1. An implantable prosthesis of shape generally similar to that of a spinal intervertebral disc <u>devoid of internal reinforcing material and rigid endplates,</u> comprised of a biocompatible elastomer with an ultimate strength in tension greater than about 100 kiloPascals, that exhibits the flexibility to allow at least <u>10</u> degrees of rotation between the top and bottom faces with torsions of at least <u>1</u> N-m without failing.

The implantable prosthesis can withstand torsion in several directions between the top and bottom faces. An exemplary result of torsional test data of a solid PVA hydrogel prosthesis is provided below.

To obtain the test data on torsion, a PVA hydrogel freeze-thaw specimen was subjected in separate test scenarios to a compressive sawtooth load waveform from 0 to 2000N for four cycles at 0.25Hz, a controlled cyclic compressive sinusoidal waveform from 800 to 2000N at 1.0Hz, a controlled sinusoidal flexion between +10° to -5° at 1.0Hz, a controlled sinusoidal axial rotation between +3.0° to -3° at 1.0Hz, and a controlled sinusoidal lateral flexion between +6° to -6° at 1.0Hz. During the latter three test scenarios the specimen was subjected to a controlled axial constant load of 1200N. The specimen was tested in a saline solution kept at 37°C and cycled through the environmental chamber of the specimen.

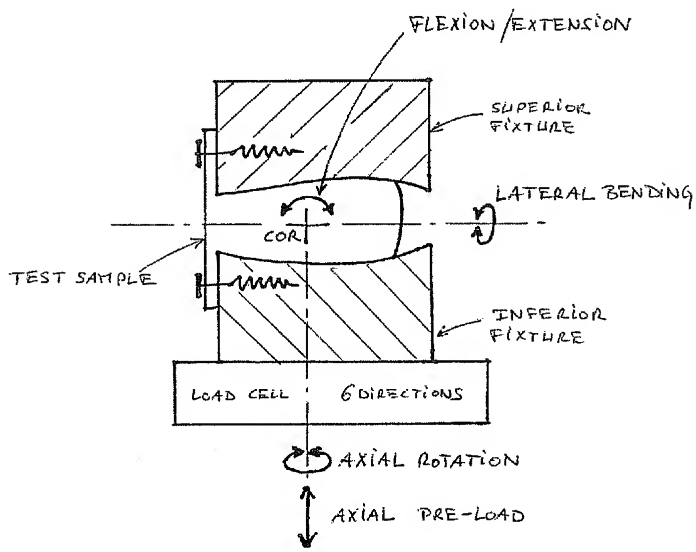
The test data revealed that the PVA implant withstood approximately 12N-m for 10 degrees in flexion, 9N-m for 6 degrees in lateral bending, and 2N-m for 3 degrees in axial rotation (without failing).

Extrapolated those values can be represented as follows:

	Stiffness N-m/deg
Flex/Ex	1.05
Lat Bend	1.49
Axial Rot	0.53

Thus, the PVA implant needs at least 10N-m for 10 deg in Flexion/Extension and Lateral Bend. That is, torsion performance includes torsion around the 'z' axis, as well as flexion/extension and lateral bending 'torsion' around x and y. In some embodiments, the PVA implant can require over 10 Nm for torsion in two directions.

A schematic of the test set-up used to obtain the torsional data used to characterize the durability of the prosthesis is provided below. The flexion/extension and lateral bending occur through the superior fixture and the axial compression and axial rotation occur through the inferior fixture. The center of rotation (COR on the sketch) is the geometric center of the core of the test sample (in an unloaded and zero displacement configuration).



Applicant respectfully submits that independent Claim 1 is patentable over Dickman. That is, unlike Dickman, which requires an internal matrix of reinforcing material to provide its durability, Claim 1 recites that the body is devoid of internal (core) reinforcing material and flexibility parameters.

In view of the foregoing, Applicant respectfully submits that Claims 1-3, 7, 9, 13-25 and 28 are patentable over Dickman.

III. The Section 103 Rejections over Dickman in view of US 5,458,643 to Oka ("Oka") and US Provisional Application 60/412,028 to Schmieding ("Schmieding") (via US 2004/0059425A1).

The Action also rejects Claims 1-7, 9, 13-26, 28, 29, 34-52, 56-69 and 71-73 as being obvious over Dickman combined with Oka and Schmieding. The Action concedes that Dickman is unspecific as to types of hydrogel polymers but states that Dickman mentions PVA hydrogel at col. 4, lines 49-55 in reference to Oka. The Action also states that Schmieding directed to cylindrical osteochondral plugs, discloses that SALUBRIA can be molded into anatomic shapes and is very suitable for orthopedic applications.

Applicant agrees that SALUBRIA is biocompatible and suitable for orthopedic uses as stated by Schmieding. However, Schmieding proposes treating the knee with a cartilage implant, which is very different from the loads, stresses and articulation requirements of a total intervertebral disc (IVD) replacement. Thus, one of skill in the art at the time of the invention would not identified SALUBRIA as material for a IVD implant based on Schmieding, which is directed to osteochondral implant material.

Further, Dickman discusses Oka in the Background of the Invention segment of the Dickman patent and asserts with respect to all of the discussed devices that "[p]rior art artificial intervertebral disks, and techniques of fastening, anchoring and stabilizing implanted artificial disks do not appear likely to yield satisfactory results" (col. 5, lines 19-21)(emphasis added). Thus, Dickman was very aware of PVA hydrogel as a biocompatible material used for IVDs, yet did not include this material as an alternative in his own description of suitable materials, which is just described as "preferably a hydrogel polymer" (col. 7, lines 30-33). Indeed, based on Dickman's own characterization of the Oka device in the Background section of his patent, Dickman (presumably one of skill in this art) appears to believe that such a material was not likely to yield satisfactory results.

Indeed, Oka proposes a composite body of PVA hydrogel with porous ceramics or titanium mesh (col. 4, line 1). Oka states that an object of a first invention is to obviate "the defects in the materials" for the conventional artificial articular cartilage while the object of a

second invention is to eliminate problems in the conventional intervertebral discs and that the objects of the first and second inventions are common in that hydrogel of PVA is used to improve dynamic characteristics (col. 3, lines 8-25). Notably, Oka goes on to state at col. 5, lines 30-35:

> To eliminate the defects of the above-mentioned intervertebral discs, the inventors of the present invention studied and experimented variously. Consequently, the inventors provide an artificial intervertebral disc comprising **a pair of metallic or ceramic porous bodies** and a polyvinyl alcohol hydrogel block incorporated therebetween.

(emphasis added). Oka also describes a preformed, rectangular-column, pure titanium fiber mesh (porosity about 50%) measuring 20x20x8 placed in a mold (col. 31-35), and also mesh of 6 mm height (col. 9, Experiment 1), mesh of 20 mm in height (col. 9, Experiment 2) and mesh of 10 mm height (col. 10, Experiment 3). As shown in Figures 2 and 3(a)-3(e), Oka proposes a small core of PVA surrounded by relatively thick mesh components. Oka also describes various PVA formulations with different shearing stresses (col. 10) using PVA composite bodies. Oka teaches away from an IVD formed by the PVA block alone (*e.g.*, devoid of ceramic or metallic body end plates).

Dickman requires the use of a fabric matrix with the polymer to form the core. Dickman also states that the IVD of Oka does not appear likely to succeed. Thus, Dickman apparently either discounts the ability of a solid PVA core to function as an IVD and/or that the PVA molded to columns of titanium mesh (6mm to 20 mm tall) is not suitable to function as an IVD.

Further, Applicant submits that if Dickman and Oka are combined, the resulting device would require a reinforced interior PVA hydrogel core formed with an interior fabric-reinforced core or a reinforced core sandwiched between metallic or porous ceramic bodies.

In contrast, *see, e.g.*, independent Claims 1, 34, 43, 48 and 63, which are restated below for ease of discussion.

> 1. An implantable prosthesis of shape generally similar to that of a spinal intervertebral disc devoid of internal reinforcing material and rigid endplates, comprised of a biocompatible elastomer with an ultimate strength in tension greater than about 100 kiloPascals, that exhibits the

flexibility to allow at least 10 degrees of rotation between the top and bottom faces with torsions of at least 1 N-m without failing.

34. An implantable non-articulating total disc replacement spinal disc body having a superior surface and an inferior surface joined by a circumferential surface, the body defined by a solid biocompatible freeze-thaw hydrogel devoid of internal reinforcement material inside the disc body with an ultimate strength in tension greater than about 100 kiloPascals that exhibits the flexibility to allow at least 2 degrees of rotation between the superior and inferior faces with torsions of at least 0.01 N-m without failing.

43. An implantable spinal total disc replacement body consisting essentially of a biocompatible solid polyvinyl alcohol (PVA) cryogel devoid of any internal reinforcing material, the body having an ultimate strength in tension greater than about 100 kiloPascals and sufficient elasticity to allow for shock absorption and flexibility of motion between adjacent vertebrae that allows at least 10 degrees of rotation between the top and bottom faces with torsions of at least 1 N-m without failing, the body shaped to have:

a substantially concave superior surface having a substantially flat periphery surface;

a substantially convex inferior surface having substantially flat periphery;

the superior and inferior surfaces being joined by a circumferential surface; and

the implantable spinal disc body being further characterized as being of a kidney shape formed by an extended oval surface and an indented portion, having a substantially rectangular cross-section, and having an anterior portion of greater thickness than a posterior portion.

48. An implantable spinal total disc replacement having a flexible non-articulating solid body devoid of endplates, the body having a nucleus and annulus that are both defined by a crystalline PVA hydrogel and is devoid of internal reinforcing material, the body having a shape generally similar to that of a human spinal intervertebral disc with opposing top and bottom faces, wherein the crystalline PVA hydrogel has an ultimate tensile and compressive strength of at least about 100 kiloPascals and exhibits sufficient flexibility to allow at least 2 degrees of rotation between the top and bottom faces with torsions of at least 0.01 N-m without failing.

63. A spinal total disc replacement prosthesis having a solid body consisting essentially of a freeze-thaw PVA cryogel that defines a core and annulus with mesh fabric moldably attached to reside on outer surfaces of

the solid body, wherein the core is devoid of internal reinforcing material, and wherein the prosthesis is non-articulating and has an ultimate tensile strength that is greater than about 100 kiloPascals.

For at least the features emphasized above, Applicant respectfully submits that the claims are patentable over the cited prior art.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Respectfully submitted,

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

Julie H. Richardson
Registration No. 40,142

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on March 16, 2007.

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Rosa Lee Brinson